

REMARKS/ARGUMENTS

Claims 10-12 have been canceled. Upon entry of this Amendment, Claims 1, 3-9 and 13-16 will be pending in the application.

Claim 1 has been amended in view of the disclosure in U.S. Pat. No. 6,440,923 and U.S. Pat. No. 6,194,372. Support for this amendment can be found in original dependent claims 10 and 12 as well as in the specification including the paragraph bridging pages 4 and 5, the paragraph bridging pages 5 and 6, and Tables I, II and III. No new matter has been included in the above amendments.

Rejections under 35 U.S.C. §102

Claims 1, 5, 6, 9, and 12 – 15 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,440,923 to Lyle et al.

Claims 1, 3-6, 9, 13, 15 and 16 are rejected under 35 U.S.C. 102(e) or 102(a) as being anticipated by U.S. Pat. No. 6,194,372 to Picken, Jr. et al.

Independent claim 1 is directed to a physically stable shear thinning sprayable gel composition useful for delivering actives to skin. The gel composition uses a clay-based gelling agent mixed with water, at least one water-miscible solvent and at least one viscosity stabilizer. The viscosity stabilizer is selected from citric acid, xanthan gum and combinations thereof. The amount of the stabilizer is critical to the overall stability of the gel composition wherein the stabilizer contained in the composition ranges from about 0.01 percent to about 0.05 percent by weight, based on the total weight of the gel composition.

In this manner, independent claim 1 includes the limitations to the effect that

- a. the shear thinning sprayable gel composition is used for delivering actives to skin;
- b. the gel composition contains a clay gelling agent, water, a water-miscible solvent and a viscosity stabilizer; and
- c. the viscosity stabilizer is selected from citric acid, xanthan gum and combinations thereof, with the amount of the stabilizer ranging from 0.01 to 0.05 percent by weight, based on the total weight of the gel composition.

Lyle et al. discloses a detergent composition for topical application.

Picken, Jr. et al. discloses a solvent based sprayable gel. The compositions of Picken, Jr. et al. and Lyle et al. are examples of the problems in the prior art that were addressed in the Background portion of the Applicants' specification, for example on page 2, lines 16-25, where it states, *"One problem associated with known sprayable gel compositions is that the compositions are not physically stable. Compositions that are not physically stable are problematic for several reasons. The composition might become too viscous to spray. The composition could also become too thin and tend to run or drip. Phase separation can also occur, leading to inappropriate concentrations of active ingredient being delivered. The stability of sprayable gel compositions may be adversely affected by the incorporation of active ingredients into the compositions."* Lyle et al. teaches a packaged aqueous self-foaming liquid cleansing composition. Picken Jr. et al. teaches a sprayable gel cleaning composition made of a solution and gel-

forming material capable of forming a gel when placed with the solution. Lyle et al and Picken Jr. et al. do not disclose, teach or suggest the use of a viscosity stabilizer made from citric acid, xanthan gum and combinations thereof, with the amount of the stabilizer ranging from 0.01 to 0.05 percent by weight, based on the total weight of the gel composition. Additionally, the specified range is critical to the stability of the gel composition of the present invention. Tables I, II and III shown below illustrate the criticality of such a range, wherein sample 1 contains the viscosity stabilizer(Citric Acid and Xanthan gum) and samples 2 and 3 do not.

Accordingly, there was no motivation or suggestion to employ such a range for the weight percentage of a viscosity stabilizer, or a combination of materials selected from citric acid and xanthan gum.

Table I

<u>Sample 1 Ingredients</u>	<u>Function</u>	<u>% (w/w)</u>
Water	-	49.65
Ethyl alcohol	Water miscible solvent	42.75
Glycerol	Emollient	4.00
Laponite XLG	Gelling agent	1.00
Menthyl Lactate	Active/Cooling agent	1.00
Menthol	Active/Topical analgesic	0.50
Camphor	Active/Topical analgesic	0.50
<u>Benzyl Alcohol</u>	Preservative	0.50
Fragrance	-	0.05
Citric Acid	Viscosity stabilizer	0.03
Xanthan Gum	Thickener	0.02
Total	-	100.00

Sample 1 was a dispersion having the composition given in Table I. The dispersion was prepared according to the following procedure:

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The dispersion of Sample 1 was prepared in a stainless steel container equipped with a stirrer. The Laponite XLG clay was added to the water and stirred under vigorous stirring for 20 minutes to form a dispersion of the clay in water. The glycerin and xanthan gum were then added with stirring for 10 minutes. The ethyl alcohol, benzyl alcohol, camphor, menthol, menthyl lactate, fragrance and citric acid were combined in a separate container and mixed until a uniform solution was obtained. The aforementioned solution was slowly added to the aqueous clay dispersion with stirring. Stirring was continued for 10 minutes to yield the finished product. The finished product was transferred to pump spray containers. The dispersion was physically stable after 13 weeks at 40°C.

Samples 2 and 3, neither of which includes a viscosity stabilizer, are comparative examples in which the compositions were not physically stable. The compositions of samples 2 and 3 are given in Tables II and III, respectively. These compositions tended undesirably to produce a ringing gel upon aging. After aging for 4 weeks at 40°C, they could not be dispensed from a pump spray bottle.

Table II

<u>Sample 2 Ingredients</u>	<u>Function</u>	<u>% (w/w)</u>
Water	-	47.90
Ethyl alcohol	Water miscible solvent	43.61
Glycerol	Emollient	5.00
Laponite XLG	Gelling agent	2.00
Menthol	Active/Topical analgesic	1.00
Camphor	Active/Topical analgesic	0.50
Total	-	100.00

Note: the preparation procedure followed that of Sample I

Table III

<u>Sample 3 Ingredients</u>	<u>Function</u>	<u>% (w/w)</u>
Water	-	48.00
Ethyl alcohol	Water miscible solvent	42.75
Glycerol	Emollient	5.00
Laponite XLG	Gelling agent	1.50
<u>Menthyl Lactate</u>	Active/Cooling agent	1.00
Menthol	Active/Topical analgesic	1.00
Camphor	Active/Topical analgesic	0.50
Fragrance	-	0.05
Xanthan Gum	Thickener	0.20
Total	-	100.00

Note: the preparation procedure followed that of Sample I

The use of thickeners, such as xanthan gum or cellulose (e.g., carboxymethyl cellulose), help mitigate the formation of a rigid gel. However, if the concentration of the thickener is too high, the composition will not dispense through a pump spray bottle. Additionally, a high concentration of thickener has a negative effect on the clarity of the compositions.

A document can only anticipate a claim if the document discloses, explicitly or implicitly, each and every feature recited in the claim. Verdagall Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since Lyle et al. and Picken et al. fail to disclose, either explicitly or implicitly, at least the above-noted feature recited in independent claim 1, Lyle et al. and Picken et al. cannot anticipate these claims. At least in view of the foregoing, claim 1 is allowable, and the rejection should be reconsidered and withdrawn. Claims 3-6, 9 and 13-16 depending from claim 1, are allowable as depending from an allowable base claim, as well as the additional features they recite. Withdrawal of this rejection is respectfully requested.

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Rejection under 35 U.S.C. §103

The rejection of Claims 3, 4, 7, 8, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Lyle has been maintained by the Examiner.

Claims 7, 8, 11 and 12 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Picken, Jr. et al.

As mentioned earlier, Claims 10-12 have been cancelled herewith.

The Office Action acknowledges that Lyle et al. and Picken Jr. et al. do not disclose or teach the claimed concentrations of weight percentage ranges for the solvent as well as the viscosity stabilizer. However, the Office Action does allege that it would have been obvious absent a showing of criticality of the claimed concentration. Applicants' respectfully disagree.

Lyle et al. and Picken, Jr. et al. do not claim a specified range for the solvent and viscosity stabilizer concentrations because neither was interested in stabilizing the gel composition over long periods of time. As discussed above, the criticality of the specified concentration range for each component is shown in samples 1, 2 and 3. Accordingly, there is no motivation in Lyle et al. or Picken, Jr. et al. to extend the stability of the composition, and therefore no need is present for a specified concentration range.

Accordingly, Lyle et al. and Picken, Jr. et al. do not disclose, teach or suggest the specified concentration range for each component, particularly the viscosity stabilizer. At least in view of the foregoing, claims 3, 4, 7 and 8 are allowable. Furthermore, claims 3, 4, 7 and 8, depending from claim 1 are allowable as depending from an allowable base claim,

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as well as the additional features they recite, particularly within the claimed combination.

Withdrawal of this rejection is respectfully requested.

Conclusion

In view of the claim amendments made herein, and further in view of the foregoing Remarks/Arguments, it is believed that the claims now pending are patentable over the references of record. Withdrawal of the rejections in the Office Action of August 5, 2003 and passage of the pending claims to issue are respectfully solicited. If the Examiner has any questions regarding this Amendment, she is requested to call Applicants' undersigned attorney at the telephone number given below.

Respectfully submitted,

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